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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/025,423	12/18/2001	Ronald N. Zuckermann	16141.003	6469

7590                    09/23/2003

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EXAMINER

WESSENDORF, TERESA D

ART UNIT	PAPER NUMBER
1639	

DATE MAILED: 09/23/2003

15

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application N</b>	<b>Applicant(s)</b>
	10/025,423	ZUCKERMANN ET AL.
	<b>Examiner</b>	<b>Art Unit</b>
	T. D. Wessendorf	1639

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1) Responsive to communication(s) filed on 26 June 2003.

2a) This action is **FINAL**.      2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213..

**Disposition of Claims**

4) Claim(s) 13-21 and 24-29 is/are pending in the application.

4a) Of the above claim(s) 18-20 is/are withdrawn from consideration.

5) Claim(s) \_\_\_\_\_ is/are allowed.

6) Claim(s) 13-17,21 and 24-29 is/are rejected.

7) Claim(s) \_\_\_\_\_ is/are objected to.

8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.  
 If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
 a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

1) <input type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ .
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>14</u> .	6) <input type="checkbox"/> Other: _____ .

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**DETAILED ACTION**

***Status of Claims***

Claims 1-12 and 30-32 have been cancelled in the present amendment (2/14/03).

Claims 18-20 are withdrawn from consideration, as stated above.

Claims 22-23 have been cancelled by the present amendment, 6/26/03.

Claims 13-21 and 24-29 are pending in the application.

Claims 13-17, 21 and 24-29 are under examination.

***Specification***

The incorporation of essential material in the specification, e.g., page 10, lines 20-29 by reference to a foreign application or patent (e.g., WO 98/06437), or to a publication is improper, as stated in the last Office action.

***Response to Arguments***

Applicants argue that the examiner has provided no reason why the incorporated material be considered "essential". The cited material provides background information on peptides, but it is not critical to the enablement or written description of the claimed subject matter.

In response, MPEP 608.01 defines "essential material" as that which is necessary to (1) describe the claimed invention, (2) provide an enabling disclosure of the claimed invention, or

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(3) describe the best mode (35 U.S.C. 112). In any application which is to issue as a U.S. patent, essential material may not be incorporated by reference to (1) patents or applications published by foreign countries or a regional patent office, (2) non-patent publications, (3) a U.S. patent or application which itself incorporates "essential material" by reference, or (4) a foreign application. The specification at page 10, lines 20-25 states that "...peptoid"....described, for example, in PCT publications ....for preparation of peptoides, see references ... Barlette, Santi...." These are foreign references or publications that describe the essential claimed peptoides. These publications and foreign references provide enabling disclosure of how to make the peptoids. The cited materials are therefore not background information on peptoids as these were described in the specification under the DETAILED DESCRIPTION OF THE INVENTION section. It appears that these are the peptoids covered by the broad scope of the claimed peptoids.

Therefore, the objection to the specification is maintained.

The objection to the specification as failing to provide proper antecedent basis for the claimed subject matter in claim 23, "non-selected cell type is an epithelial cell" is moot with the cancellation of claim 23.

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***Claim Rejections - 35 USC § 112, first paragraph***

Claims 13 and 15 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The specification fails to provide support and written description for step (iii) of the claimed method in claim 13 or a plurality of distinct cell types in claim 15. Applicants point support at page 11, lines 9-10 of the specification for claim 13. The cited section of the specification does not relate to said identification of the transfected cells. Applicants rely at page 21, lines 8-24 of the instant specification. The cited section recites for three specific tumor cells. However, the presently amended "plurality of distinct cell types" would be broader in scope than the three recited tumor cells.

***Claim Rejections - 35 USC § 112, second paragraph***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

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The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 13-17 and 21, 24-29 are rejected under 35

U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention for reasons advanced in the last Office action.

The rejections under paragraphs A-E have been overcome with the amendment to the claims and applicants' arguments.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 13-17 and 21, 24-25 and 27-29 are rejected under 35 U.S.C. 102(b) as being anticipated by Murphy et al (PNAS, 2/98) for reasons advanced in the last Office action.

Murphy et al discloses at page 1517, col. 1 and col. 2 and page 1518, RESULTS section heading up to page 1522, a method of identifying transfection peptoids comprising screening a diverse library of cationic N-substituted glycine peptoids oligomer of

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varying chain length (library of peptoids, as claimed). The peptoids is then complexed with DNA, transfecting cells lines such as the tumor cell lines NIH3T3, HT 1080 and COS cells with the peptoid-DNA complex. The N-terminal modified peptoids (i.e., peptoid-lipid conjugate) is shown at Table 1 and 2, page 1519. Screening for those peptoids that mediated transfection of the cell lines are shown in Fig. 5, page 1521. The peptoids that transfected the cells are identified at page 1521, col. 1 and col. 2. Accordingly, the method of Murphy employing specific method steps and components fully meets the broad claimed process steps and components.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 13-17 and 21-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Murphy in view of Fasbender et al (US 5,935,936) for reasons advanced in the last Office action.

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***Response to Arguments***

Applicants admit that Murphy describes identification of cationic peptides which are effective in the delivery of plasmid DNA (pCMV-km-LUC). The pCMV is alleged as described in U.S. Patent No. 6,468,986 as over 4,000 bp. But argue that the plasmid DNA would clearly not be considered an "oligonucleotide" as the term is known to those skilled in the art as a short sequence of nucleotides. The present specification is argued to define oligonucleotide as preferably between about 10 and 50 in length.

In response, applicants' arguments are not commensurate in scope with the claims. Applicants cannot read limitations set forth in the specification to the claims. While the specification defines the oligonucleotide length the claims do not. Claims should be given their broadest reasonable interpretation. Thus, while the plasmid DNA of Murphy contains a 4,000 bp, the Luc gene might be an oligonucleotide. Even if the Luc gene were a polynucleotide, however, one would have been motivated to use an oligonucleotide since Murphy discloses that this long chain polynucleotide are subject to degradation on delivery to the target site. One skilled in the art knows that these polynucleotides are normally condensed into its oligonucleotide to protect it from enzyme degradation,

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especially in vivo delivery. Murphy discloses that the peptoids condenses the polynucleotide to a smaller size. In such condensation and degradation, the DNA may have been converted to its smaller fragments, oligonucleotides. This would be at least suggestive of the claimed oligonucleotides. In the absence of new and unexpected results in delivering an oligonucleotides as opposed to a polynucleotide using the same delivery system of peptoids, the claimed invention is *prima facie* obvious to one having ordinary skill in the art.

[Incorporating the limitation of claim 14 and the length of the oligonucleotide in claim 13, as argued, would render the claim allowable].

No claim is allowed.

#### **Conclusion**

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS

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of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

This application contains claims 18-20 drawn to a non-elected invention. A complete reply to the final rejection must include cancelation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to T. D. Wessendorf whose telephone number is (703) 308-3967. The examiner can normally be reached on Flexitime.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on (703) 306-3217. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-7924 for regular communications and (703) 308-7924 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

T.D. W  
T. D. Wessendorf  
Primary Examiner  
Art Unit 1639

tdw

September 22, 2003